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Appendix 5

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30 October 2000

Dr. James T. Elfstrum
Manager, Regulatory Affairs
Rhodia Inc.
CN 7500
Cranbury, NJ 08512-7500

Re: GRAS Status of Beta-Glucan Soluble Fiber

Dear Jim:

This letter is written in response to your request concerning the GRAS status of beta glucan soluble fiber and purified forms thereof at concentrations up to 25 % beta glucan soluble fiber.

Beta glucan is derived by enzymatic and/or acid/base hydrolysis from oat bran or oat flour. Alpha-amylase (carbohydrase) is the enzyme used and it is derived from Aspergillus niger. This enzyme is considered GRAS although the FDA has not officially listed it as GRAS. Other agents used in the process are food grade. The theoretical upper limit for beta glucan soluble fiber from oat bran and oat flour is up to 25 % beta glucan soluble fiber. The functionality of beta glucan in various products is as a water-binder, humectant, or texture modifier. The maximum concentration of beta glucan in the proposed products will not exceed 25 %.

ConAgra informed the Agency of its independent GRAS assessment of beta glucan in 1991. The proposed concentration of beta glucan soluble fiber was up to 15%. This limit was based on technical considerations and not on toxicological findings. Based on available information, it appears that the USFDA and the USDA have informally agreed that beta glucan soluble fiber is GRAS.

Neither a list of proposed products nor estimated intakes was available. The recommended intake from proposed uses is 3 g or more per day of beta glucan fiber from whole oats or purified extracts having up to 25 % beta glucan soluble fiber.

Beta glucan soluble fiber is naturally occurring. Products containing beta glucan soluble fiber have been consumed for a number of years without evidence of adverse effects. There is no reported toxicity at grams/kg bw doses. The stool-softening effects of soluble fibers are well known and desirable.

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Following a critical evaluation of information provided and other materials deemed appropriate or necessary, it is concluded that beta glucan soluble fiber produced and used in accordance with current Good Manufacturing Practices and meeting the specifications described is GRAS for use as a water-binder, humectant, or texture modifier at concentrations up to 25% in various products.

In my opinion, other scientists qualified by experience and/or training to evaluate the safety of foods and food ingredients, would also conclude that beta glucan produced and used as a water binder, humectant, or texture modifier in accordance with current Good Manufacturing Practices at concentrations up to 25 % in various products is GRAS.

Thank you for the opportunity to provide assistance.

Sincerely,

Joseph F. Borzelleca